

## SUMMARY OF INTERVIEW

### Attendees, Date and Type of Interview

The telephonic interview was conducted on February 4, 2010 and attended by Ja-na Hines and Che Chereskin.

### Exhibits and/or Demonstrations

Two proposed claim amendments were faxed to the Examiner prior to the interview.

### Identification of Claims Discussed

Claim 1

### Identification of Prior Art Discussed

Dalemans, et al. (WO 99/30733)

### Proposed Amendments

1) An amendment to present the protein and adjuvant as a single composition to emphasize that they are pre-mixed as follows:

Claim 1-1. **(Proposed)** An immunogenic composition suitable for administration to a vertebrate host which comprises:

(a) a composition comprising a protein antigen immunogenic component comprising at least one protein antigen selected from the group consisting of model protein antigens and immunogenic protein antigens and a mineral-based, negatively charged adjuvant; and

(b) a polynucleotide immunogenic component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said polynucleotide immunogenic component into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response; said composition produced by a method comprising preincubating or subsequently mixing said mineral-based negatively charged adjuvant

with said at least one protein antigen immunogenic component to form the composition of (a) prior to formulating with said polynucleotide immunogenic component.

2) An amendment to (c) to : "a composition consisting of one adjuvant,...". to emphasize that additional adjuvants / slow release agents are not included.

#### Principal Arguments and Other Matters

Dalemans, et al. do not teach pre-mixing the protein and negatively-charged mineral adjuvant. Dalemans, et al. teach additional adjuvants and slow release agents, not a single adjuvant. The proposed amendments are believed to address the rejection under 35 U.S.C. § 102.

Regarding obviousness, Applicants have submitted evidence (Attachment with the last response) as well as evidence provided in the specification as filed (graph on page 6 of published application, corresponding to page 12 of present specification) that show a dramatic difference between use of a positively charged mineral-based adjuvant and a negatively charged mineral-based adjuvant. Dalemans, et al. does not distinguish between positively charged and negatively charged mineral-based adjuvants at all. Accordingly, the results achieved by Applicants were unexpected.

#### Results of Interview

The Examiner agreed that either proposed amendment would move the present 102 rejection to 103.

Regarding specifically proposed claim 1-1, the Examiner pointed to the statement in Dalemans, et al. at page 4, lines 13-14 that "Optionally, the polypeptide may be adjuvanted as well", but noted that Dalemans, et al. here do not teach specifically a "mineral-based, negatively charged adjuvant" as per Applicants' claims, so that she would not consider this statement as anticipating for proposed claim 1-1.

The Examiner also appeared to agree that the data presented for negatively charged mineral-based adjuvants by Applicants (compared to positively charged mineral-based adjuvants) demonstrated an unexpected result.